CDRH SUBMISSION COVER SHEET

Date of Submission: **FDA Document Number:**

Section A — Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
Original Submission ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission Summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	Original Submission: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Report Amendment	☐ Pre-IDE mtg. ☐ Pre-PMA mtg. ☐ Pre-PDP mtg. ☐ 180-Day mtg. ☐ Other (specify):
IDE ☐ Original submission ☐ Amendment ☐ Supplement	Humanitarian Device Exemption ☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	Class II Exemption ☐ Original Submission ☐ Additional Information	Evaluation of Automatic Class III Designation ☐ Original Submission ☐ Additional Information	Other Submission Describe Submission:

Section B — Applicant or Sponsor

Company/Institution Name:		Establishment registration number:	
Division Name (if applicable):		Phone number (include area code):	
Street Address:		Fax number (include area code):	
City:	State/Province:	Zip code:	Country:
Contact Name:			
Contact Title:		Contact e-mail address:	

Section C — Submission Correspondent (if different from above)

Company/Institution Name:		Establishment registration number:	
Division name (if applicable)		Phone number (include area code):	
Street Address:		Fax number (include area code):	
City:	State/Province:	Zip Code:	Country
Contact Name:			

Section D1 **Reason for Submission – PMA,PDP, or HDE**

☐ New Device
☐ Withdrawal
☐ Additional or Expanded Indications
☐ Licensing Agreement

☐ Change in design, component, or specification:
- ☐ Software
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other (specify below)

☐ Location Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager
- ☐ Distributor

☐ Processing Change:
- ☐ Manufacturing
- ☐ Sterilization
- ☐ Packaging
- ☐ Other (specify below)

☐ Labeling Change:
- ☐ Indications
- ☐ Instructions
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other (specify below)_

☐ Report Submission:
- ☐Annual or Periodic
- ☐ Post Approval Study
- ☐ Adverse Reaction
- ☐ Device Defect
- ☐ Amendment

☐ Response to FDA correspondence:
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site

☐ Change in Ownership
☐ Change in correspondent

☐ Other Reason (specify):

Section D2 **Reason for Submission - IDE**

☐ New device
☐ Addition of institution
☐ Expansion/extension of study
☐ IRB certification
☐ Request hearing
☐ Request waiver
☐ Termination of study
☐ Withdrawal of application
☐ Unanticipated adverse effect
☐ Notification of emergency use
☐ Compassionate use request
☐ Treatment IDE
☐ Continuing availability request

Change in:
- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer
- ☐ Manufacturing process
- ☐ Protocol – feasibility
- ☐ Protocol – other
- ☐ Sponsor

☐ Report Submission:
- ☐Current investigator
- ☐ Annual progress
- ☐ Site waiver limit reached
- ☐ Final

☐ Response to FDA letter concerning:
- ☐ Conditional approval
- ☐ Deemed approval
- ☐ Deficient final report
- ☐ Deficient progress report
- ☐ Deficient investigator report
- ☐ Disapproval
- ☐ Request extension for time to respond to FDA
- ☐ Request meeting

☐ Other reason (specify):

Section D3 **Reason for Submission – 510(k)**

☐ New Device
☐ Additional or expanded indications
☐ Other reason (specify):

☐ Change in technology
☐ Change in design

☐ Change in materials
☐ Change in manufacturing process

Section E **Additional Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data: ☐ 510(k) summary attached ☐ 510(k) statement
1	2	3	4	
5	6	7	8	

510(k) Number	Trade of Proprietary or model name	Manufacturer
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F **Product Information – Applicable to All Applications**

Common or usual name or classification name:

Trade or proprietary or model name	Model Number
1	1
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

Section G **Product Classification – Applicable to All Applicants**

Product code:	C.F.R. Section	Device Class: ☐ Class I ☐ Class II ☐ Class III ☐ Unclassified
Classification Panel:		
Indications (from labeling):		

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H **Manufacturing/Packaging/Sterilization Sites Relating to a Submission**

☐Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler
Company/Institution name:		Establishment registration number:
Division name (if applicable):		Phone number (include area code):
Street address:		FAX number (include area code):

City	State/Province	Zip code:	Country
Contact name:			
Contact title:			

☐ Original ☐ Add ☐ Delete	FDA Establishment registration number:	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler
Company/Institution Name:		Establishment registration number:
Division name (if applicable):		Phone number (include area code):
Street address:		FAX number (include area code):

City:	State/Province:	Zip code:	Country:
Contact name:			
Contact title	Contact e-mail address:		

☐ Original ☐ Add ☐ Delete	FDA Establishment registration number:	☐ Manufacturer ☐Contract sterilizer ☐ Contract Manufacturer ☐Repackager/relabeler
Company/Institution name:		Establishment registration number:
Division name (if applicable):		Phone number (include area code):
Street address:		FAX number (include area code):

City:	State/Province:	Zip code:	Country:
Contact name:			
Contact title	Contact e-mail address:		